

General

Guideline Title

Practice parameters for anal squamous neoplasms.

Bibliographic Source(s)

Steele SR, Varma MG, Melton GB, Ross HM, Rafferty JF, Buie WD, Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for anal squamous neoplasms. *Dis Colon Rectum*. 2012 Jul;55(7):735-49. [195 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Fleshner PR, Chalasani S, Chang GJ, Levien DH, Hyman NH, Buie WD, Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for anal squamous neoplasms. *Dis Colon Rectum* 2008 Jan;51(1):2-9. [82 references]

Recommendations

Major Recommendations

The levels of evidence and the grades of recommendations (1A-2C) are defined at the end of the "Major Recommendations" field.

Anal Canal Squamous-Cell Carcinoma (SCC)

Pretreatment Evaluation

1. A disease-specific history should be performed, emphasizing symptoms, risk factors, and signs of advanced disease. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
Risk factors associated with anal SCC include infection with the human papillomavirus (HPV), human immunodeficiency virus (HIV) seropositivity, history of other HPV-related genital malignancies (cervical cancer, cervical intraepithelial neoplasia [CIN], vulvar cancer, or vulvar intraepithelial neoplasia); previous sexually acquired diseases, cigarette smoking, anoreceptive intercourse, multiple sexual partners, history of solid organ transplant, and other forms of immunosuppression. Because the incidence of anal cancer is higher in men practicing anoreceptive intercourse with men and those with HIV positivity, a high index of suspicion should be maintained in these patients presenting with anorectal complaints. Although potentially sensitive and difficult, inquiry to establish the presence or absence of these risk factors is important. Certain factors such as previous radiation, general medical issues, or inadequately controlled HIV may prove to be limiting or contraindications to chemoradiation therapy (CRT) or radical surgery, and are important to determine at the time of diagnosis.
2. A disease-specific physical examination should be performed to determine size, possible lymph node involvement, or metastatic disease. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.

Physical examination should focus primarily on the anorectal examination and evaluation of the inguinal and femoral nodes. Digital rectal examination should be performed to identify the lesion location and to evaluate for fixation and the presence of sphincter invasion. Perirectal lymph nodes may be sometimes palpable. Anoscopy or proctoscopy with biopsy is essential to establish the size of the lesion, to determine the location within the anal canal, and to confirm diagnosis. Presence of palpable inguinal lymphadenopathy can suggest the need for fine-needle aspiration or core biopsy to confirm malignant involvement and help guide radiation fields. In general, metastatic disease is difficult to detect on physical examination, although a complete physical examination should be performed to help identify any potential sites of distant spread that may warrant further evaluation.

The American Joint Commission on Cancer (AJCC) local-regional staging for SCC of the anal canal focuses on the primary lesion size, the existence of local invasion, and the presence or absence of regional node disease. As such, clinical evaluation including size is critically important to determine proper staging (see Table 2 in the original guideline document). Invasion of the anal sphincter or perianal skin does not constitute a T4 lesion; however, this should be determined to aid in potential alterations in treatment.

3. Endoscopic and radiologic evaluation should be performed to help determine staging, and concomitant or metastatic disease. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.
Biopsy should be performed under direct vision or through an anoscope or sigmoidoscope. Although anal cancer is not a risk factor for the development of colon cancer, colorectal neoplasms have been demonstrated in up to 15% of patients with anal cancer; therefore, colonoscopy should be performed to rule out synchronous colorectal neoplasms based on standard age and risk profile assessment. Chest, abdomen, and pelvic computed tomography (CT) should be performed to evaluate for lymphadenopathy, in particular, inguinal lymph node radiographic abnormalities that may warrant biopsy, and to exclude lung and liver metastases. Because SCC can metastasize not infrequently to the brain, head CT may be performed if clinical symptoms suggest involvement. In addition, evaluation of the primary tumor may be considered. Endoanal ultrasound (EAUS) and MRI are presently the 2 most accepted modalities and may be useful in determining primary tumor depth, evaluating sphincter involvement, and evaluating perirectal lymph node involvement, with data reporting increased accuracy and sensitivity over physical examination alone. MRI is comparable to EAUS for primary tumor size and nodal status and may be considered. Although not typically a part of the routine evaluation, ¹⁸F-fludeoxyglucose positron emission tomography/CT (FDG-PET/CT) has been shown to identify distant metastases that are not detected by physical examination or other imaging modalities in 17% to 25%, resulting in a reported change in treatment (i.e., radiotherapy) in up to 5% to 19% of cases.
4. Sentinel lymph node evaluation for detection of regional nodal metastases is still investigational. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.

Treatment

Primary Treatment

1. The primary treatment for most SCCs of the anal canal should be combined modality CRT. Grade of Recommendation: Strong recommendation based on high-quality evidence, 1A.
 - Intensity-modulated radiation therapy-based chemoradiotherapy (IMRT) may be considered to decrease treatment-related toxicity. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.
2. Multidrug chemotherapy including mitomycin-C (MMC) and 5-fluorouracil (5-FU) along with radiation is usually preferable to other chemotherapy regimens with radiation. Grade of Recommendation: Strong recommendation based on high-quality evidence, 1A.
3. Higher doses of radiation therapy without prolonged breaks in treatment are preferable when tolerated. Grade of Recommendation: Weak recommendation based on moderate-quality evidence, 2B.

Treatment of Recurrent or Persistent Disease

1. Abdominoperineal resection is effective salvage therapy for persistent or recurrent disease. Grade of Recommendation: Strong recommendation based on moderate-quality evidence, 1B.
2. Systemic chemotherapy should be considered in patients with extrapelvic metastasis or recurrence following surgical salvage. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Management of Inguinal Lymph Node Disease

1. Chemoradiation is the treatment of choice for inguinal lymph node disease. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
With the identification of any positive inguinal lymph node, bilateral inguinal basins should be incorporated into the radiation fields with the addition of a boost technique. Metachronous lymph nodes are seen in 10% to 20% of patients, normally within 6 months of completing

treatment of the primary lesion. These metachronous nodes should also be treated with CRT, and typically respond well. Elective prophylactic lymphadenectomy is generally not warranted and is associated with high wound complication rates as well as lower-extremity complications. Selective inguinal node dissection may be considered for persistent disease following CRT.

Anal Cancer in HIV-Positive Patients

1. CD4 counts may be used to predict the outcome and tolerance of CRT in HIV-positive patients: Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.

There is some controversy regarding CD4 count and correlation with outcome and toxicity, but, in general, this may be used for HIV-positive patients as a general guide along with clinical assessment. Patients with CD4 counts >200 cells/mL should typically be treated similarly to non-HIV-infected patients with anal cancer with the use of chemoradiation. CD4 counts <200 cells/mL have been shown to have higher toxicity, and treatment should be individualized. Treatment with highly active antiretroviral therapy allows patients to better tolerate CRT and may improve local control, although higher overall rates of both acute and long-term toxicities have been reported.

Posttreatment Surveillance

1. Follow-up examination should typically include anorectal examination including digital rectal examination, anoscopy, and inguinal palpation. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Anal cancers regress both during and after CRT; therefore, follow-up should generally commence 6 to 12 weeks after the completion of treatment. Patients should normally be followed up at 3 to 6 months for the first 2 years, 6 to 12 months until 5 years, and annually thereafter, with varying intervals dictated by clinical findings. Recurrences are often amenable to further treatment that may result in cure. In general, at a minimum anorectal examination should consist of visual inspection, digital rectal examination, and anoscopy, along with inguinal palpation. Lesions occurring 3 or more months after the completion of primary CRT are concerning for persistent disease and should be biopsied because digital examination alone is unreliable for confirming residual malignancy.

2. Imaging studies such as endoanal ultrasound (EAUS), computed tomography (CT), magnetic resonance imaging (MRI), and ¹⁸F-fluorodeoxyglucose positron emission tomography/CT (FDG-PET/CT) should be considered for posttreatment surveillance to assess for persistent or recurrent disease. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Anal Margin Squamous-Cell Carcinoma

1. A disease-specific history and physical examination should be performed, emphasizing risk factors, tumor size, location, and signs of advanced disease. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Staging of anal margin cancers by AJCC criteria follows that of skin cancer elsewhere, based on tumor size and lymph node involvement. Evaluation should consist of a perianal examination, including digital rectal examination, anoscopy, and palpation of the femoral and inguinal lymph node basins. T1-3 are staged the same manner as SCC of the anal canal, but T4 signifies invasion of deep extradermal structures such as bone, nerve, striated muscle, or cartilage. N0 and N1 refer to no regional or regional lymph node spread. In general, CT of the chest, abdomen, and pelvis should be done to assess for distant metastasis.

Treatment of anal margin SCC varies depending on size and depth of invasion. In general, T1 and early T2 lesions can be adequately treated with wide local excision (WLE) with a 1-cm margin, although close proximity to the anal canal may make this difficult. Definitive treatment by WLE alone for these early lesions has been associated with 5-year survival rates up to 88%. Primary radiation, combined with chemotherapy, is also an option, albeit less effective than appropriate excision. Small series with radiation alone have demonstrated failure rates of up to 36%. Larger cancers usually should be treated with upfront radiation to the inguinal nodal basins along with radiation or excision of the primary tumor. For T3 and T4 lesions, radiation to both inguinal regions and the pelvis along with chemotherapy with the use of 5-FU and MMC or cisplatin should normally be added. Abdominoperineal resection (APR) may be required for larger and deeper, less favorable lesions (T2-4 or N1), those involving the sphincter muscles, patients with incontinence, or patients with multiple recurrences after local excision. Salvage therapy for treatment failure after local excision can include repeat local excision, APR, and/or radiation therapy with or without chemotherapy. Accounting for size and location, tumors of the anal margin, especially larger ones, are associated with lower rates of overall and colostomy-free survival in comparison with anal canal lesions.

Low-Grade and High-Grade Anal Intraepithelial Neoplasia (LGAIN/HGAIN)

Pretreatment Evaluation

1. A disease-specific history and physical examination should be performed for LGAIN/HGAIN, emphasizing symptoms, risk factors, and location of disease. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
2. Anal Papanicolaou (Pap) smear cytological examination may be useful in the detection and follow-up of LGAIN/HGAIN. Grade of

Recommendation: Strong recommendation based on low-quality evidence, 1C.

Screening procedures for LGAIN/HGAIN include anal cytology, colposcopy, biopsy, and high-resolution anoscopy (HRA). Based on numerous similarities between LGAIN/HGAIN and CIN, anal Pap smear cytology consists of using anal swabs to sample cells from the canal and has been instituted for both screening high-risk individuals and as surveillance after treatment for LGAIN/HGAIN.

Treatment

1. Observation alone with close clinical follow-up may be considered in select cases for the management of LGAIN/HGAIN. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.
2. Topical 5% imiquimod cream with close long-term follow-up is an appropriate therapy for LGAIN/HGAIN of the anal margin. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
3. Topical 5% 5-FU cream with close long-term follow-up is an appropriate therapy for LGAIN/HGAIN. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
4. Photodynamic therapy with close long-term follow-up may be appropriate therapy for select patients with LGAIN/HGAIN. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.
5. Targeted destruction and close clinical long-term follow-up is appropriate therapy for LGAIN/HGAIN. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.
6. Patients with LGAIN/HGAIN should be offered close long-term clinical follow-up. Grade of Recommendation: Strong recommendation based on low-quality evidence, 1C.

Patients with LGAIN/HGAIN should typically be monitored for the development of recurrence, persistence, or progression to anal cancer. Surveillance examinations may be performed at 3- to 6-month intervals as long as dysplasia is present. This approach allows for the treatment of recurrent or persistent dysplasia or the detection of invasive anal SCC. Follow-up generally includes digital rectal examination, anoscopic examination, with or without the aid of magnification or the application of acetic acid and Lugol solution, and can be performed in an office setting. Anorectal cytology and/or biopsy may also be included, as indicated. The importance of close follow-up should be particularly emphasized among high-risk cohorts such as HIV-positive patients, patients with a history of other HPV-related genital malignancies, recipients of solid organ transplants, or men who have sex with men (MSM) who have been shown to have higher risk of persistence or recurrence of high-grade dysplasia (up to 80%) regardless of treatment modality.

7. Vaccination against human papillomavirus (HPV) 16/18 may be considered in high-risk patients such as HIV-positive patients and MSM. Grade of Recommendation: Weak recommendation based on low-quality evidence, 2C.

Definitions:

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) System—Grading Recommendations^a

	Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A	Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B	Strong recommendation, moderate-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C	Strong recommendation, low- or very-low-quality evidence	Benefits clearly outweigh risk and burdens or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A	Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burdens	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B	Weak recommendations, moderate-quality evidence	Benefits closely balanced with risks and burdens	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values

2C	Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
	Weak recommendation, low- or very-low-quality evidence	Uncertainty in the estimates of benefits, risks and burden; benefits, risk and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

RCT = randomized controlled trial

^aAdapted from Guyatt G, Gutterman D, Baumann MH, et al. Grading strength of recommendations and quality of evidence in clinical guidelines: report from an American College of Chest Physicians Task Force. Chest. 2006;129:174–181.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Anal squamous neoplasms

Other Disease/Condition(s) Addressed

Human immunodeficiency virus (HIV)

Guideline Category

Evaluation

Management

Risk Assessment

Treatment

Clinical Specialty

Colon and Rectal Surgery

Oncology

Radiation Oncology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Patients

Physician Assistants

Guideline Objective(s)

To provide practice parameters for the evaluation and treatment of anal squamous neoplasms

Target Population

Adults with anal squamous neoplasms

Interventions and Practices Considered

Anal Canal Squamous-Cell Carcinoma

Evaluation

1. Disease-specific history and physical examination, including assessment of risk factors, comorbidities, and digital rectal examination (DRE)
2. American Joint Commission on Cancer locoregional staging
3. Endoscopic and radiologic evaluations (anoscopy, sigmoidoscopy, colonoscopy, endoanal ultrasound [ERUS], computed tomography [CT], ¹⁸F-fludeoxyglucose positron emission tomography/CT [FDG-PET/CT])
4. Histology of mass
5. CD4 counts for patients with human immunodeficiency virus (HIV)

Treatment

1. Combined chemoradiation therapy
2. Intensity-modulated radiation therapy-based chemoradiotherapy (IMRT)
3. Multidrug CRT (5-FU plus mitomycin C)
4. Higher dose radiation in selected cases
5. Abdominoperineal resection for persistent or recurrent disease
6. Systemic chemotherapy for extrapelvic metastasis or recurrence after surgery
7. Highly active antiretroviral therapy (HAART) plus CRT for patients with HIV
8. Posttreatment surveillance/follow-up

Anal Margin Squamous-Cell Carcinoma

1. Disease-specific history and examination, as above
2. Tumor staging as for skin cancer
3. Wide local excision for T1/T2 tumors
4. CRT with 5-FU plus mitomycin C or cisplatin for T3/T4 lesions
5. Abdominoperineal resection in selected cases

Anal Intraepithelial Neoplasia (AIN)

Evaluation

1. Disease-specific history, physical examination, and risk assessment
2. Anal Papanicolaou smear cytologic examination

Treatment

1. Observation alone
2. Topical 5% imiquimod or 5% 5-FU cream
3. Photodynamic therapy
4. Targeted destruction by surgical ablation or infrared coagulation (IRC) and close clinical follow-up
5. Long-term follow-up

Major Outcomes Considered

Response rate
Local control rate
Recurrence rate
Overall survival
Disease-free survival
Colostomy-free survival
Side effects
Specificity and sensitivity of diagnostic tests

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

These guidelines are built on the last set of the American Society of Colon and Rectal Surgeons Practice Parameters for treatment of anal squamous neoplasms published in 2008. An updated organized search of MEDLINE, PubMed, EMBASE, and the Cochrane Database of Collected Reviews was performed through June 2011. Keyword combinations included "AIN," "anal cancer," "anal malignancy," "anal carcinoma," "anal intraepithelial neoplasia," "Bowen's disease," "anal margin," "anal canal," "LSIL," "HSIL," "Nigro protocol," "HPV," "human papilloma virus," "vaccination," "anal surgery," "chemotherapy," "radiation therapy," and "squamous-cell cancer." Directed searches of the embedded references from the primary articles were also performed in selected circumstances. Although not exclusionary, primary authors focused on all English language articles and studies of adults.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

See the "Rating Scheme for the Strength of the Recommendations" field, below.

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

These guidelines are built on the last set of the American Society of Colon and Rectal Surgeons Practice Parameters for treatment of anal squamous neoplasms published in 2008. Recommendations were formulated by the primary authors and reviewed by the entire Standards Committee. The final grade of recommendation was performed with the use of the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system (see the "Rating Scheme for the Strength of Recommendations" field).

Rating Scheme for the Strength of the Recommendations

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Cost Analysis

- Although some economic modeling studies have suggested that frequent anal cytology may be a cost-effective method to prevent anal cancer, there have not been any randomized or cohort studies to demonstrate improved survival or outcomes.

- Similar to studies of human papillomavirus (HPV) in adolescent girls, models utilizing vaccination in men who have sex with men (MSM) beginning at age 12 without previous HPV exposure has demonstrated the cost-effectiveness of this approach to prevent infection with HPV, genital warts, and ultimately anal squamous-cell carcinoma (SCC).

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Lower rates of local failure or tumor recurrence
- Reduced need for colostomy
- Higher rates of disease-free and overall survival
- Early detection of recurrent anal squamous neoplasia

Potential Harms

- Radiation-induced toxicity (i.e., hematological, skin, diarrhea)
- Combined modality chemoradiation therapy has been associated with an increased incidence of hematological toxicity.
- Major wound complications after abdominoperineal resection (APR) are common, reported in 36% to 80%, although muscle flap use at the time of reconstruction has been associated with significantly lower rates.
- Side effects of topical iniquimod include irritation, burning, and erosions, which may adversely affect patient compliance.
- High rates of disease recurrence and anal incontinence or stenosis with wide excisional therapy of anal intraepithelial neoplasia (AIN)
- Local side effects of 5% topical 5-fluorouracil cream are very common, occurring in up to 85%, and include skin irritation and hypopigmentation, yet rarely result in discontinuation of therapy.
- Anal cytology in high-risk cohorts such as men who have sex with men (MSM) has false-negative cytology in up to 23% of HIV-negative and 45% for HIV-positive patients.
- Human immunodeficiency virus (HIV) patients with CD4 counts <200 cells/ml tend to experience higher toxicity from CRT.

Contraindications

Contraindications

Certain factors such as previous radiation, general medical issues, or inadequately controlled human immunodeficiency virus (HIV) may prove to be limiting or contraindications to chemoradiation therapy (CRT) or radical surgery, and are important to determine at the time of diagnosis.

Qualifying Statements

Qualifying Statements

- These guidelines are inclusive and not prescriptive. Their purpose is to provide information on which decisions can be made, rather than dictate a specific form of treatment.
- It should be recognized that these guidelines should not be deemed inclusive of all proper methods of care or exclusive of methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of all of the circumstances presented by the individual patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Foreign Language Translations

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2008 Jan (revised 2012 Jul)

Guideline Developer(s)

American Society of Colon and Rectal Surgeons - Medical Specialty Society

Source(s) of Funding

American Society of Colon and Rectal Surgeons

Guideline Committee

Standards Practice Task Force of the American Society of Colon and Rectal Surgeons

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Financial Disclosures/Conflicts of Interest

Not stated

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Guideline Availability

Electronic copies: Available from the [American Society of Colon and Rectal Surgeons Web site](#) .

Print copies: Available from the ASCRS, 85 W. Algonquin Road, Suite 550, Arlington Heights, Illinois 60005.

Availability of Companion Documents

None available

Patient Resources

The following is available:

- Anal cancer. Available in [English](#) and [Spanish](#) from the American Society of Colon and Rectal Surgeons (ASCRS) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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